

IHI JU guidance to Coordinators on how to prepare the Periodic technical report – Part A in Horizon Europe grants















Document history

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1. Introduction

The purpose of this document is to provide practical guidance to the coordinators (COO) of IHI JU projects on how to fill in Part A of the Periodic Report. It focuses especially on the particularities of the IHI JU that need to be considered, as highlighted in the blue boxes "IHI tips". So please read carefully.

This guide complements the Funding and Tenders Portal <u>IT How To</u> (online manual) for Horizon Europe (HE) which is the main source of information.

1.1 What is the Periodic Report?

The Periodic Report/Final Report is the pre-condition for receiving payments; it must be submitted through the EU Funding & Tenders Portal Grant Management System by the Coordinator within 60 days after the end of the reporting period.

The Report is divided into a technical and financial report. The Technical Report consists of 2 parts:

- Part A contains structured tables with project information
- Part B is a narrative description of the work carried out during the reporting period.

Part A is generated by the IT system. It is based on the information you enter into the Portal Continuous and Periodic Reporting modules.

Part B needs to be uploaded as a PDF on the Technical Report (Part B) screen. The template to use is available here.

The Financial Report is generated by the IT system on the basis of the financial information entered into the Periodic Reporting module.

1.2 How to prepare and submit it?

The Periodic Report must be prepared by the Consortium in the Continuous and Periodic Reporting modules and then be submitted by the Coordinator.

The Continuous Reporting module is always open and can be updated at any moment during the project (submit deliverables, report on milestones, etc.). It automatically feeds into Part A of the Periodic Report.

Make sure that all the information in the Continuous Reporting module is updated before 'locking the periodic report for review'. Updates entered after this step will be included in the Periodic Report of the following period (if any).

2. Project Summary (for publication)



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Project summary.

This section gives an overview of your project and its objectives and aims to promote the dissemination and support the exploitation of EU co-funded results.

This project summary will be automatically published on the <u>CORDIS</u> website (hyperlink structure such as: https://cordis.europa.eu/project/id/[project number]) so make sure that you do not include confidential information.

IHI tips

The summary serves as a window to the outside world for the project, so make sure to provide information that is **up-to-date information and understandable by a general audience**.

As this is an IHI project, ensure that the text highlights the public-private partnership nature of your project.

The information may be re-used by the IHI JU on other communication channels.

2.1 Context and overall objectives

Describe the context and overall objectives and the expected impact of your project. The description should be seen as "setting a scene for the story" of the project.

2.2 Work performed and main achievements

Describe the activities performed and the main achievements, focusing only on technical and scientific aspects (communication and dissemination activities will be mentioned in other tabs). This section is cumulative and should be updated before the submission of the periodic report, with updates related to the period under assessment.

At the end of your project, please include the outcomes of the action.

IHI tips

The work performed is a narrative description of the progress from the beginning of the project throughout the periods. This section needs to be up-to-date.

Make sure to highlight tangible achievements.

When explaining the work performed, **do not refer to Work Packages** since this would not be meaningful to the general public.

2.3 Results beyond the state of the art

Describe results, potential impacts and indicatively - if applicable- identify the key needs to ensure further uptake and success (e.g. further research, demonstration, access to markets and finance, commercialisation, IPR support, internationalisation, supportive regulatory and standardisation framework, etc.).

This section is cumulative and should be updated before the submission of the periodic report, with updates related to the period under assessment.

At the end of your project, please include an overview of the results providing links to these results as relevant.

IHI tips

This section can be organised as a **list of tangible key results**, where each result has a clear title description and link if available.

If the results are being **exploited**, please briefly explain. For example, if a patent has been generated by the project, the patent should be mentioned with its reference and its related exploitation.

2.4 Policy relevance of your project

Please describe (if applicable) the policy relevance of your project. How can the project outcomes contribute to

developing, strengthening, or improving EU policy priorities? What are your main policy recommendations/ messages and or contributions to implementing policy priorities based on the project outcomes?

Note: Policy relevant evidence and outcomes are any data, information, (scientific) advice generated by the project which could strengthen and support policy makers in developing their policies, policy measures and the implementation thereof.

IHI tips

As a reminder, IHI's projects are expected to contribute to EU programmes, initiatives and policies such as:

the Industrial Strategy for Europe, the Pharmaceutical Strategy for Europe, the European Green Deal, Europe's Beating Cancer Plan, the EU Mission on Cancer, the European Virtual Human Twins Initiative, the European Health Emergency Preparedness and Response Authority (HERA), the European Health Data Space (EHDS), and the EU Artificial Intelligence Act

3. Project Management and Implementation

3.1 Researchers involved in the project



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Researchers involved in the project.

All the researchers involved in the project should be listed under this section. Every beneficiary (and affiliated entity) should have at least one researcher declared (unless properly justified). The list is cumulative and should include all the researchers that were once part of the project.

Researchers are defined as professionals engaged in the conception or creation of new knowledge. They conduct research and improve or develop concepts, theories, models, techniques instrumentation, software, or operational methods.

The information provided in this section is used by Horizon Europe to monitor a Key Impact Pathway (KIP) on "Strengthening human capital in R&I" (For more information see the <u>Evidence Framework for the monitoring and evaluation of Horizon Europe</u>).

IHI tips

The initial **researchers list** is already filled from the GAP stage.

The **contract duration** field is mandatory when adding new researchers.

Please **update the list** and **add new researchers** involved in the project (if any) at least before the submission of the periodic report with the information available.

Please ensure also to update the list if an amendment was submitted during the reporting period adding new beneficiary(ies).

Remember the list is cumulative so do not delete researchers that are no longer part of the project. delete.

3.2 List of Deliverables



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Deliverables.

Submit here the deliverables when due.

Maximum one file per deliverable should be uploaded (the allowed formats for the file are doc, docx, odt, rtf, pdf, csv, zip).

Add actual delivery dates (or new due date for late deliverables, together with an explanation for the delay).

IHI tips

The deliverables need to follow the **IHI template available** here. Deliverables should be of sufficient quality or will be rejected.

In case of any delay, provide a **justification in the comments box** (see how to do so in the section "Comments" of the "IT How To") and a new indicative delivery date.

Pay attention to the **dissemination level**; public deliverables (to be published on Cordis website) should not include any sensitive (e.g. financial, protected, GDPR, etc.) or too specific (confidential) information.

Public deliverables should be a **stand-alone document** and understandable. For example, acronyms should be spelled out. Please also ensure that any hyperlinks included in the deliverable are valid.

Please also explain deviations in the technical periodic report under the relevant WP.

Wait for **IHI approval before publishing** deliverables in project websites, as modifications may be requested.

3.2.1 Data Management Plan

The Data Management Plan deliverable should follow the Horizon Europe DMP template.

The first version of the DMP (M6) should contain high-level description of strategy and presentation of the status (e.g. list the types of data used in the project), broad level on data info (type/format/volume/utility), description of responsibility and data preservation, backup, recovery, storage, archiving and transfer of sensitive data, information on how ethics requirement have been addressed in relation to Data Protection.

The final version of the DMP should contain information on full data catalogue, how to find data, who can have access to data, how data interoperability will be facilitated, licence, quality assurance and data reusable for long time, clear description of responsibility and data preservation, backup, recovery, storage, archiving and transfer of sensitive data. If any, the deliverable should also contain information on personal data protection update.

IHI tips

When available, the DMP deliverable should contain information on how to find data, who can have access to data, how data interoperability will be facilitated, licence, quality assurance and data reusable for long time.

Consult the IMI <u>FAIR Cookbook</u> to help you to make and keep data **Findable**, **Accessible**, **Interoperable** and **Reusable**; in one word FAIR.

The DMP should also contain the references and/or registration numbers of the **repositories** where the data has been deposited.

Consortia are strongly encouraged to use for example the HMA-EMA Catalogues of real-world data sources and studies. The HMA-EMA RWD Catalogues are repositories of metadata collected from real-world data (RWD) sources and RWD studies.

3.2.2 IHI Project outputs deliverables

The "project outputs" deliverables are specific to IHI JU.

A set of KPIs (Key Performance Indicators) specific to IHI are in place to measure the progress made by IHI projects towards the IHI objectives.

IHI JU monitors the KPIs by assessing the "project output" deliverable that each project coordinator must submit to IHI every year to capture over time the novelties and inventions developed by the projects. The data at project level will not be made public, but IHI JU may share aggregate information in an anonymised way.

IHI tips

Every **twelve months**, the IHI Project output deliverable is due.

To complete it, fill up the **questionnaire for reporting the project outputs** in the <u>SOFIA application</u>. Specific instructions are sent by email to the Coordinator and are available in the application.

Once completed, a PDF with your answers will be generated by the application; this PDF must be uploaded as the deliverable in the continuous reporting.

It is **essential that all project outputs are captured in this document**, as it will serve as the basis for the IHI JU to assess the project and the programme's progress and achievements toward its objectives. Even if some sections of the continuous report overlap with the outputs, please ensure that **all relevant outputs** are included in this deliverable.

3.2.3 Clinical study deliverables

If clinical studies are planned during the project, three mandatory Clinical Study deliverables are requested: Study initiation package, Midterm recruitment report, Report on status of posting results. Further information on the mandatory deliverables can be found in <a href="the-three-t

IHI tips

As a reminder, irrespective of the successful completion of the clinical study, **summary results must be posted in the applicable registry/ies** (where the study was registered) even if the timing of posting of results falls outside of the grant period. The report is to be scheduled for the time results posting is expected or for the last months of the project, whichever comes earlier.

In accordance with international standards, the **posting of results** should be within **one year from the end of the clinical study**.

3.2.4 Plan for the Dissemination and Exploitation of Results including Communication Activities

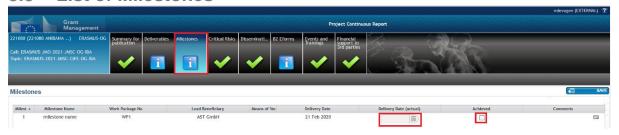
All IHI JU projects are expected to provide a 'plan for the dissemination and exploitation of results including communication activities' (PDECA), as a distinct deliverable within the first 6 months of the project. This plan should be updated during the project lifetime, as relevant. This plan should include a record of activities related to dissemination and exploitation that have been undertaken and those still planned.

IHI tips

When required by the call text, this deliverable description should refer to the specific conditions on **Availability**, **Accessibility** and **Affordability** ('3A').

The mid-term PDECA should be updated with a revised 3A strategy. This update should be based on the **progress of the clinical studies** conducted or to be conducted as part of the project and include any pertinent action to be implemented both during the project and over the four years after project end.

3.3 List of Milestones



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Milestones .

Update the status of the milestones that have been achieved by checking the box and add new due date for late milestones.

IHI tips

In case of **delay**, provide a **justification** and a **new indicative delivery date** via a comment in the Continuous Reporting.

Please also explain deviations in the technical periodic report under the relevant WP.

3.4 List of Critical Risks



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Critical Risks.

At the end of each period beneficiaries should give the state of play of every risk identified in Annex 1 and if necessary provide new mitigation measures. Moreover, additional unforeseen risks should be added during project implementation as required.

The Critical Risks tab should be used to encode the data about the state of play for foreseen and unforeseen risks and proposed mitigation actions concerning them.

IHI tips

For the critical risks that have materialised, make sure to explain what the consortium put in place to manage and overcome the challenges and what the impact is on the achievement of the project objectives.

4. Project pathway to impact

4.1 Publications



See the "IT How To" in the EU Funding & Tenders Portal on <u>Completing the Publications</u>. List here the publications that have been generated from the project.

The beneficiaries must disseminate their results as soon as feasible and when relevant through open access

peer-reviewed scientific publications. Please see Article 17 of the Horizon Europe General Model Grant Agreement (MGA, p. 110-112) and Annex 5 of the Horizon Europe Annotated Model Grant Agreement (AGA, p. 153 - 162 - dedicated section on 'Open Science') for guidance on how to comply with the open science obligations required in the Model Grant Agreement. Publications are part of the Horizon Europe Key Performance Indicators (KPIs).

The Publications tab will display a list of **Suggested publications from OpenAIRE**. If the publication is linked to the project, it should be added to **Project publications**.

In case of publications not registered via OpenAIRE, you need to encode the Digital Object Identifier (DOI) and all the rest of information is completed automatically.

IHI tips

Please ensure that appropriate acknowledgment of IHI JU funding is included as well as a disclaimer.

Include the funding acknowledgement:

"This project is supported by the Innovative Health Initiative Joint Undertaking (IHI JU) under grant agreement No [Number]. The JU receives support from the European Union's Horizon Europe research and innovation programme and COCIR, EFPIA, EuropaBio, MedTech Europe and Vaccines Europe [and [insert name(s) of the contributing partner(s) participating in the project.]"

Include the disclaimer:

"Funded by the European Union, the private members, and those contributing partners of the IHI JU. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the aforementioned parties. Neither of the aforementioned parties can be held responsible for them."

For more information, please check the <u>IHI project guidelines for the dissemination of results</u> and IHI communication guidance.

Only **project-related publications** should be included here, i.e. any publication from one of the partners not derived from the project should not be included.

All publications should have a valid link to a repository different to the publisher. Institutional, subject-based and centralised repositories are all acceptable repositories

4.2 Results



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Results questionnaire.

Provide details about project results generated during the implementation.

This list should indicate which **results** have been produced by the project, such as for example Products, Scientific discoveries, or Industrial processes, etc.

The information provided in this section is used by Horizon Europe to monitor a Key Impact Pathway (KIP) on "Addressing EU policy priorities & global challenges through R&I" and "Delivering benefits and impact through R&I missions" (For more information see the <u>Evidence Framework for the monitoring and evaluation of Horizon Europe</u>).

IHI tips

Although the categories do not match fully, please make sure to **align as much as possible** the content of this tab and the other sections containing other results types with the "**Project outputs**" declared in the Project outputs deliverable Also indicate whether the result is considered a **Key Result (KER)** because it has a **high potential** (whether the impact is scientific, social, technological, or regulatory).

It is mandatory to submit a '**results ownership list**' with the last Periodic Report (see Annex 5 of Model Grant Agreement). The submission of the last Periodic Report will be blocked if the 'results ownership list' is not filled in.

Please do not forget that you are obliged under the Grant Agreement to use the **Horizon Results Platform** to find interested parties to exploit your KERs if you have not been able to exploit them within one year after the end of the project (unless the obligation has been waived by the granting authority). **Exploitation efforts** must be continued up to **four years after the end of the project**, even when the Horizon Results platform is used.

4.3 Dissemination and Communication activities

4.3.1 Dissemination activities



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Dissemination Activities.

List the dissemination activities carried out in the context of the project. Include both the dissemination activities planned in the DoA and new ones.

The questionnaire concerns the public disclosure of the Project results via dissemination activities by any appropriate means (other than resulting from protecting or exploiting the results).

4.3.2 Communication activities



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Communication Activities .

List the communication activities carried out in the context of the project. Use the same labels used in your Dissemination Exploitation and Communication (DEC) plan.

The information provided in this section is used by Horizon Europe to monitor a Key Impact Pathway (KIP) on "Fostering diffusion of knowledge and open science" (For more information see the <u>Evidence Framework for the monitoring and evaluation of Horizon Europe</u>).

IHI tips

Both **lists of activities are cumulative**; once a dissemination/communication activity with the 'Delivered' status has been included, it will be also included in the next periodic report but without the possibility to modify it.

Focus on **highlighting impactful dissemination and communication activities**; there's no need to include every minor activity.

Remember to include a **reference to IHI JU funding** in all communication materials related to the project. For more information, please check the IHI <u>communication guidance.</u>

4.4 Standards



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Standards Questionnaire.

List the standardisation activities that result from the project.

The information provided in this section (and the following ones, 5.5, 5.6, 5.7, 5.8 and 5.9) is used by Horizon Europe to monitor Key Impact Pathways (KIP) on "Addressing EU policy priorities & global challenges through R&I" and "Generating innovation-based growth" (For more information see the <u>Evidence Framework for the monitoring and evaluation of Horizon Europe</u>).

IHI tips

Although the categories do not match fully, please make sure to **align as much as possible** the content of this tab and the other sections containing other results types as well as the "**Project outputs**" declared in the Project outputs deliverable.

4.5 Intellectual Property Rights (IPR)



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Intellectual Property Rights (IPR)

The Intellectual Property Rights (IPR) tab manages the intellectual property rights. The tab was previously named Patents (IPR).

List the IPRs (patents, trademarks, registered designs, utility models or others) that have resulted from the project.

IHI tips

If the IPR is confidential, you can mark it as such and indicate the date in which the embargo period is lifted.

Use the application reference to search for patents and get the data filled in automatically.

Although the categories do not match fully, please make sure to **align as much as possible** the content of this tab and the other sections containing other results types as well as the "**Project outputs**" declared in the Project outputs deliverable.

4.6 Datasets



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Datasets (Horizon Europe).

Enter the information related to datasets that have been generated during the implementation of the project.

The Datasets tab will list automatically a list suggested by OpenAIRE. If those are linked to the project they need to be imported and will show in the Project Datasets.

IHI tips

Although the categories do not match fully, please make sure to **align as much as possible** the content of this tab and the other sections containing other results types as well as the "**Project outputs**" declared in the Project outputs deliverable.

When relevant, the datasets/databases should also be included in the <u>HMA-EMA Catalogues</u> of real-world data sources and studies.

4.7 Impact



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Impact questionnaire.

The Impact questionnaire manages project information about: Technology readiness; Sustainable Development Goal (SDGs) and Overall Citizen engagement.

Please provide data to complete all necessary fields in each section and related sub-tabs of the questionnaire.

IHI tips

The IHI JU contributes to the United Nations Sustainable Development Goal (SDG) 3 on **ensuring healthy** lives and promoting well-being for all at all ages.

Patient engagement is a priority of the IHI JU. Please also include under the section on citizen engagement the activities in which patients were involved.

Align with project summary and other section of the reporting.

4.8 Impact (continuation)



See the "IT How To" in the EU Funding & Tenders Portal on Completing the Impact continuation .

The **Impact continuation** tab gathers information about scientific, societal, environmental, and economic impact(s) resulting from the Project's implementation. This information is intended to supplement what's already listed under the Impact Questionnaire tab (see 5.7) with a special focus on potential investments (public, private, blended) that can result in the launch of a dedicated company.

IHI tips

Be concise and align with the impact section of the core report (Part B).

Align with project summary and other sections of the reporting.

4.9 Other Results



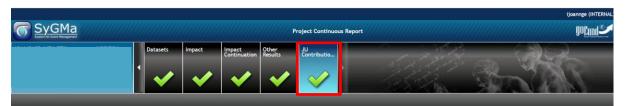
See the "IT How To" in the EU Funding & Tenders Portal on <u>Completing the Other Results questionnaire</u>. The Other Results questionnaire should list the Project results other than those included in the Results tab. The type of results considered here are: software; workflow; protocol; prototype; other.

IHI tips

Although the categories do not match fully, please make sure to **align as much as possible** the content of this tab and the other sections containing results as well as the "**Project outputs**" declared in the Project outputs deliverable.

Align with project summary and other sections of the reporting.

4.10 JU Contributions



See the "IT How To" in the EU Funding & Tenders Portal on Completing the JU Contributions.

This tab is specific to IHI Private Members and Contributing Partners and captures their cumulative contributions (i.e. IKOP, non-EU IKOP, Financial Contribution Given) effectively brought since the start of the project.

For each IHI Private Member and Contributing Partner (irrespectively of their participation as beneficiary, affiliated entity or associated partner case b), the cumulative amount of contribution in euros needs to be encoded.

- In-kind contributions to Operational Activities (IKOP): amount (in EUR) of in-kind contribution to operational activities, consisting of the reported costs minus the requested EU contribution, if any.
- **Non-EU IKOP**: part of IKOP (in EUR) incurred in third countries outside the 27 EU Member States and Associated countries to Horizon Europe.
- Financial Contributions Given: amount (in EUR) of financial contribution paid to another beneficiary

(eligible to received EU funding) to implement the project.

IHI tips

The data is **cumulative** and must therefore reflect the total contributions brought since the start of the project.

Ensure **IKOP** is correctly calculated: the value of IKOP in the 'JU Contribution' tab must correspond to the cumulative reported costs minus the cumulative requested EU contributions (if any) as reported in the **financial statement(s)** for each of the concerned entities¹ since the start of the project.

The amount of **Non-EU IKOP** is included in the IKOP and shall be consistent with section 6 of the technical report Part B.

The amount of **Financial Contribution Given** shall be consistent with section 5 of the technical report Part B

Please note that the **In-kind contributions to Additional Activities (IKAA)** is not reflected in the 'JU Contribution' tab in the Continuous reporting. If relevant, the **IKAA** is reported in a different module via the Funding and Tenders Portal (specific instructions on IKAA reporting are available in the <u>IKAA guidelines</u>).

¹ In the particular case of Associated Partners case b, they have no financial statement and their costs are reported in the financial statement of their designated beneficiary. The designated beneficiary is therefore responsible for specifying the cumulative IKOP of its

Associated Partners case b in the 'JU Contribution' tab.